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Medtronic Sofamor Danek
CENTERPIECE™ Plate Fixation System
510(k) Summary - K050082
May 2005

Submitter:	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132
Contact Person:	Richard Treharne (901) 396-3133
Common Name:	Appliance, Fixation, Interlaminal
Trade Name:	CENTERPIECE™ Plate Fixation System
Classification:	21 CFR 888.3050: Spinal interlaminal fixation orthosis. Product Code: NQW
Device Description:	The CENTERPIECE™ Plate Fixation System consists of a variety of sizes of plates and screws. The CENTERPIECE™ Plate Fixation System components are made of from medical grade titanium or titanium alloy.
Intended Use:	The CENTERPIECE™ Plate Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The CENTERPIECE™ Plate Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.
Functionality & Safety Testing:	Mechanical testing was performed on the CENTERPIECE™ Plate Fixation System and was included in this submission.
Substantial Equivalence	The CENTERPIECE™ Plate Fixation System is substantially equivalent to a previously cleared device used to perform laminoplasty procedures, namely the Kirschner Orthopedic Wire, K850631 Kirschner Medical Corp. (SE 05/01/85).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 - 2005

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek Incorporated
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K050082
Trade/Device Name: CENTERPIECE™ Plate Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: NQW
Dated: April 8, 2005
Received: April 11, 2005

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050082

Device Name: CENTERPIECE™ Plate Fixation System

Indications for Use:

The CENTERPIECE™ Plate Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The CENTERPIECE™ Plate Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050082